MAR 1 2002

K014300
Page 1 of 2

510(k) Summary

Submitter and Contact Person

Dr. James D. Rusin MD, MBA
3512 Rum River Drive
Anoka, MN 55303-1109
Cell# 612-242-8037
Fax# 763-712-8706
Submitted 12/15/01

Device Name

Trade Name: SafeTouch
Common Name: Breast Exam Recording Sheet
Proprietary Name: SafeTouch
Classification: None

Equivalent Device

Docuform produced by Derma Solutions of Angola, IN

Device Description

Thin plastic film with a preprinted numbered grid and orientation markings

Intended Use

The device is intended to assist medical examiners in reproducibly representing the location of discovered breast lumps.

Device comparisons

Our device, SafeTouch, and the Docuform device have the same intended use.
Each device incorporates the use of a supple plastic film to be place over the breast containing the suspect lesion. A mark is made upon each device over the suspect lesion in the breast.
SafeTouch is preprinted with orientation marks and a numbered grid.
Docuform contains no orientation marks and no grid.
In the case of Docuform, the mark on the supple film is transferred to a permanent firm plastic sheet, which is meant to become part of the patient's permanent record.

Nonclinical Performance

In our tests, a soft, supple film is necessary for the performance of the device and for patient comfort and acceptance. The preprinted, numbered grid greatly improves the reproducibility of the findings and allows for the use of a new grid sheet with each examination if desired by the examiner or the patient.

i. ***SafeTouch*** utilizes preprinted marks for orientation, whereas Docuform relies upon examiners applying orientation marks 'freehand'.
ii. ***SafeTouch*** is larger than Docuform.
iii. Docuform incorporates a series of steps whereby the mark upon the supple film is transferred to a hard vinyl film, which becomes part of the permanent record.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 1 2002

Dr. James D. Rusin MD, MBA
3512 Rum River Drive
ANOKA MN 55303-1109

Re: K014300
Trade/Device Name: SafeTouch Breast Exam Recording Sheet
Regulation Number: None
Regulatory Class: Unclassified
Product Code: 85 NHM
Dated: December 20, 2001
Received: December 31, 2001

Dear Dr. Rusin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: K014300

Device Name: SafeTouch Breast/Body Recording Sheet

Indications For Use: SafeTouch is intended as an aide in relocating points of interest discovered upon the human body, once they are found. A typical application would be to indicate the location of discovered human breast lumps.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

David G. Eyman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K014300

Prescription Use ✓
(Per 21 CFR 801.109)